PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

	Date of mailing *(day/month/year)* 26.11.2004
Applicant's or agent's file reference JNR/PG4885	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/08151	23.07.2003	25.07.2002

Applicant
GLAXO GROUP LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	HAEMAELAEINEN, E Tel. +49 89 2399-

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JNR/PG4885	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/08151	International filing date *(day/month/year)* 23.07.2003	Priority date *(day/month/year)* 25.07.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant GLAXO GROUP LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27.01.2004	26.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Azaïzia, M Telephone No. +49 89 2399-6960

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/08151

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-60 as originally filed

Claims, Numbers

1-37 as originally filed

Drawings, Sheets

1/15-15/15 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	7, 10-22, 24-37
	No:	Claims	1-6, 8, 9, 23
Inventive step (IS)	Yes:	Claims	7
	No:	Claims	1-6, 8-37
Industrial applicability (IA)	Yes:	Claims	1-37
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:
   D1: US-B-6 234 167 (2001-05-22)
   D2: WO-A-02/04055 (2002-01-17)
   D3: WO-A-03/061744 (2003-07-31)

2. Independent claims 1 and 37 appear to comprise all the features of independent claim 23 and are therefore not appropriately formulated as a claims dependent on the latter (Rule 6.4 PCT). For the purposes of this report, claims 1 and 37 have thus been considered as dependent on claim 23.

3. The present application does not meet the requirements of the PCT, because the subject-matter of claim 23 is not new in the sense of Article 33(2) PCT.
   The document **D1** already discloses (the references in parentheses applying to this document) a medicament pack (see fig.3) for use with a medicament dispenser ("aerosol generator 121"), the pack comprising:
   - a first medicament container ("source 37 of material") containing plural co-formulation compatible medicament components (see column 9, line 52 to line 55); and
   - at least one further medicament container ("source 137 of second material"), each **implicitly** containing at least one co-formulation incompatible medicament component (see column 8, line 47 to line 50); and,
   - wherein the at least one co-formulation incompatible medicament component is kept separate (see column 8, line 47 to line 50) from the plural co-formulation compatible medicament components.
   (see also c.8, l.47 to c.9, l.12, fig.3 and c.9, l.52-66)

   The subject-matter of claim 23 is therefore not new (Article 33(2) PCT).

3.1 The subject-matter of claim 23 is also not new (Article 33(2) PCT) with regard to the disclosure of document **D2** which already discloses (the references in parentheses applying to this document) a medicament pack ("fluid cartridge 58" shown in fig.9) for use with a medicament dispenser ("nebulizing device 2"), the pack comprising:
   - a first medicament container (one of the two compartments, see p.5, l.3-4, fig.9) containing plural co-formulation compatible medicament components (see p.1, l.14

to p.2, l.2 and in particular p.2, l.1-2); and
- at least one further medicament container (the other of the two compartments, see p.5, l.3-4, fig.9), each containing at least one co-formulation incompatible medicament component; and,
- wherein the at least one co-formulation incompatible medicament component is kept separate (by the "separate compartments", see p.5, l.3-4, and fig.9) from the plural co-formulation compatible medicament components.

The subject-matter of claim 23 is therefore not new (Article 33(2) PCT).

4. Claims 1-6, 8-22 and 24-37 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty (Article 33(2) PCT) and/or inventive step (Article 33(3) PCT), the reasons being as follows:

4.1 The additional features of claims 1-6, 8 and 9 are already known from D2 (see the passages cited in the search report) so that these claims also lack novelty (Article 33(2) PCT)

4.2 The additional features of claims 10-22 and 24-36 appear to define merely one of several straightforward possibilities (depending on the desired type of therapy) from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill. The subject-matter of these claims lacks therefore an inventive step (Article 33(3) PCT).

4.3 Claim 37 defines the medicament pack of claim 23 where the medicament containers are parts of a kit. This is considered to be a slight constructional change which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claim 37 lacks an inventive step (Article 33(3) PCT).

5. The document **D1**, which is considered to represent the most relevant state of the art, discloses (cf. paragraph 3 above) a medicament dispenser device for use in the delivery of a multi-component combination medicament product, wherein the medicament components of said multi-component combination medicament product are kept separate until the point of release thereof for delivery in combination. The subject-matter of dependent claim 7 differs from this known medicament dispenser device in that the first and the at least one further medicament container are of a

different type (see the present description - page 3, line 4 to page 4, line 4 - page 6, line 16 to page 8, line 5). The subject-matter of dependent claim 7 is therefore new (Article 33(2) PCT).
Moreover, a medicament dispenser device according to dependent claim 7 enables convenient, combined delivery of the components of a combination medicament product to a patient since particular medicaments and combinations thereof can be more suited for formulation and delivery by particular types of inhaler device. That suitability may, for example, be driven by ease of formulation of the medicament for that particular inhaler or by the delivery and pharmaceutical performance characteristics obtainable when the particular inhaler device is employed.

The problem to be solved may be regarded as "how to provide a medicament dispenser device which enables convenient, combined delivery of the components of a combination medicament product to a patient".
The solution to this problem proposed in dependent claim 7 of the present application is considered as involving an inventive step (Article 33(3) PCT) since it cannot be derived in an obvious manner from the prior art: all the documents cited in the search report disclose medicament dispenser devices, wherein the medicament containers are of similar type. None of these documents gives an indication to the person skilled in the art about that suitability for formulation and delivery of particular medicaments by particular types of inhaler device.

6. The subject-matter of claims 1-37 is considered industrially applicable since it can be made or used in any kind of industry (Article 33(4) PCT), such as the medical industry for example.

------ Certain documents cited ------

7. The document **D3** was cited by virtue of Rule 64.3 PCT. The following data (Rule 70.10 PCT) concerning this document are given:

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO 03/061744	31.07.2003	22.01.2003	25.01.2002 25.07.2002

------- Certain defects in the international application (form and content) -------

8. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents **D1** and **D2** is not mentioned in the description, nor are these documents identified therein.

9. The independent claim should be drafted in the two-part form in accordance with Rule 6.3(b) PCT, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

10. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

------- Certain observations on the international application (clarity) -------

11. Dependent claims 34-36 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. In fact, these claims define a medicament dispenser device by reference to claims defining a medicament pack. For the purposes of this report, dependent claims 34-36 have been considered as being directed to a medicament pack (according to claim 33).

12. Although claims 23 and 37 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims lack conciseness and as such do not meet the requirements of Article 6 PCT.

13. In order to overcome this objection, it would appear appropriate to file an amended set of claims defining the relevant subject-matter in terms of a single independent claim in each category followed by dependent claims covering features which are merely optional (Rule 6.4 PCT).

14. It is pointed out that an invention entitles the applicant to a unique and single patent. Nevertheless, it seems that the applicant has filed two different applications for the same invention since an overlapping in the subject-matter claimed in the current application WO2003/EP08151 and the application WO2003/EP08152 exists (see for

example claim 7 of WO2003/EP08151 and claim 1 of WO2003/EP08152). The applicant may be required in the national phase to choose for each application a different invention to continue with for the procedure or to choose which one of those applications he wishes to proceed to grant (see the PCT Guidelines - as in force from 9 October 1998 - Section IV, Chapter IV, 6.3).